

REMARKS

Claims 1-15 are pending in the application. Claim 7 is herein amended.

No new matter has been added. It is respectfully submitted that this Amendment is fully responsive to the Office Action dated October 3, 2008.

Claim Rejections – 35 U.S.C. §102

Claims 7-9 were rejected under 35 U.S.C. §102(b) as being unpatentable over Masamura et. al. (Arterioscler. Thromb. Vasc. Biol. 2003; 23:512-517.) Applicants respectfully traverse this rejection.

Masamura et al. discloses a process of adding pitavastatin, which is one of the isoprenoid synthesis inhibitor, to human umbilical vein endothelial cells (HUVECs). It further discloses that the administration of pitavastatin led to an increase in cellular thrombomodulin antigen and mRNA levels.

However, the transfer of Cdc42 protein into the nucleus was not disclosed in Masamura et al.

The presently claimed method comprises the step of administering an isoprenoid synthesis inhibitor and/or a geranylgeranyl transferase inhibitor into the cell and transferring the Cdc42 protein from outside a nucleus of the cell into the nucleus of the cell. The present patent application specification discloses that Cdc42 protein is transferred to the nucleus after culturing HUVECs administered with pitavastatin.

Masamura et al. does not disclose the process of transferring Cdc42 protein into the nucleus.

Applicants submit that Masamura et al. would not be able to confirm the transfer of Cdc42 protein into the nucleus since Masamura et al. does not recognize that the behavior of Cdc42 protein changes.

Thus, Masamura et al. does not disclose teach, suggest or provide any reasoning of the presently claimed method. Favorable reconsideration is earnestly solicited.

Claim Rejections – 35 U.S.C. §102

Claims 7-9 were rejected under 35 U.S.C. §102(b) as being unpatentable over Morikawa et. al. (J. Atheroscler Thromb., 2002; 9: 178-183.) Applicants respectfully traverse this rejection.

Morikawa et al. discloses a process of adding pitavastatin, which is one of the isoprenoid synthesis inhibitor, to human umbilical vein endothelial cells (HUVECs). It further discloses analyzing gene wherein the expression level changes by the administration of pitavastatin, This is achieved by using DNA microarrays.

However, Morikawa et al. does not disclose the transfer of Cdc42 protein into the nucleus.

Applicants submit that Morikawa et al., as well as Masamura et al, would not be able to confirm the transfer of Cdc42 protein into the nucleus since Masamura et al. does not recognize that the behavior of Cdc42 protein changes.

Therefore, Morikawa et al. does not disclose teach, suggest or provide any reasoning of the presently claimed method. Favorable reconsideration is earnestly solicited.

Claim Rejections – 35 U.S.C. §112

Claims 7-9 were rejected under 35 U.S.C. §112 first paragraph, as being unpatentable for failing to enable one of ordinary skill in the art to practice the claimed invention. Applicants respectfully traverse this rejection.

Statins, such as pitavastatin, are widely used for the treatment of hypercholesterolemia since it inhibits the synthesis of cholesterol. Statins inhibit the cholesterol synthesis of HUVECs cultured in vitro, while lowering the cholesterol level in blood in vivo.

The response of HUVECs to statins clearly reflects the response of a biological body wherein statins are administered. The culture of HUVECs is one of the most representative models in studying statins.

Therefore, one skilled in the art is able to understand and practice the presently claimed method of transferring Cdc42 protein into the nucleus, based on the description of Example 1 of the present patent specification using HUVECs.

Applicants respectfully submit that the presently claimed method is enabled and one of ordinary skill in the art would be able to practice the presently claimed method. Favorable reconsideration is earnestly solicited.

Claims 7-9 are rejected under 35 U.S.C. §112 second paragraph as being unpatentable for being indefinite. Applicants respectfully traverse this rejection.

A Cdc42 protein is a low-molecular weight G protein belonging to the Rho family. It generally exists in cell cytoplasm and acts as a secondary messenger.

The presently claimed method localizes the Cdc42 protein from the cytoplasm to the inside of the nucleus, thereby sequestering the Cdc42 from the place where it originally functions.

As a result of the presently claimed method, the Cdc42 protein is inactivated.

The presently claimed method is able to screen substances that regulate signal transmission pathway through Cdc42.

The mechanism through which the presently claimed method works is not germane to the pending application. Such a disclosure is irrelevant to patentability and is beyond what is required of Applicants.

Applicants submit that that the presently claimed method is sufficiently definite. Favorable reconsideration is earnestly solicited.

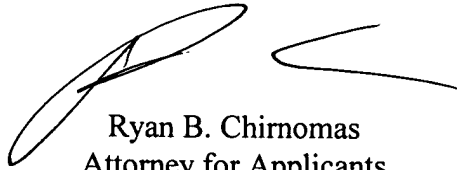
In view of the aforementioned amendments and accompanying remarks, Applicants submit that the claims, as herein amended, are in condition for allowance. Applicants request such action at an early date.

If the Examiner believes that this application is not now in condition for allowance, the Examiner is requested to contact Applicants' undersigned attorney to arrange for an interview to expedite the disposition of this case.

If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP

A handwritten signature in black ink, appearing to read 'Ryan B. Chirnomas', is written over the printed name and title.

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